REMARKS

Claims 1-9, 11-14, and 17-19 are pending in this application. Claim 1 is the only independent claim

The Examiner indicated that claims 13, 17, and 19 contain allowable subject matter. *See* Office Action, p. 4. Applicant notes with appreciation the Examiner's indication of allowable subject matter.

In the outstanding Office Action, the Examiner rejected claims 1, 2, 5-9, 12, 14, and 18 under 35 U.S.C. § 102(b) as being anticipated by Klatt et al. (U.S. Patent No. 3,788,296); rejected claims 1-5 and 8 under 35 U.S.C. § 102(b) as being anticipated by Millar et al. (U.S. Patent No. 4,449,980) and rejected claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Klatt et al.

Applicant respectfully traverses the rejection under 35 U.S.C. § 102(b) because neither Klatt et al. nor Millar et al. discloses all of the elements recited in the claims. For example, neither Klatt et al. nor Millar et al. discloses a substance delivery device including "a support frame having at least two resilient arms which retain said device in the body cavity, wherein each resilient arm is capable of receiving and releasing a separate substance delivery means capable of releasing substance into the body cavity, and wherein the arms are biased outward from a central section of the support frame," as recited in independent claim 1.

Klatt et al. discloses a device designed for applying active substance in or on the nasal septum. As such, it is not suitable for total insertion into a body cavity. For example, if inserted in a vagina, the Klatt device may exert pressure on the vaginal mucosa and cause ischaemic necrosis. Potentially, such an insertion into a vagina may

also cause vaginal wall necrosis and vaginal perforation. Unlike the Klatt device, the substance delivery device recited in independent claim 1 includes resilient arms so that the device can be retained in a body cavity, such as a vagina, without any severe injury thereto.

Klatt et al. furthermore fails to disclose "each resilient arm . . . capable of receiving and releasing a separate substance delivery means." In Klatt et al., the drug substance is incorporated onto the device as a non-removable polymer. The Klatt device is therefore not reusable and is not capable of "receiving and releasing" a substance delivery means.

Moreover, Klatt et al. fails to disclose "the arms . . . biased outward from a central section of the support frame." The Examiner alleges that the arms of the Klatt device are biased outward "because they would inherently tend to exert outward forces when they are pushed toward each other due to their resiliency." Office Action, p. 2. Applicant respectfully traverses this inherency rejection because the arms of the Klatt device are not necessarily and inevitably "biased outward." For example, as illustrated in Fig. 1, the Klatt device is a nasal clamp designed to be fixed by "pressing of the clamp onto the nasal septum." Col. 3, lns. 29-31. To be fixed to the nasal septum, the arms of the Klatt device should not exert outward forces when they are pushed toward each other. Otherwise, the Klatt device would not be fixed to the nasal septum. For at least this reason, the arms of the Klatt device are not inherently "biased outward."

Like Klatt et al., Millar et al. also fails to disclose "each resilient arm . . . capable of receiving and releasing a separate substance delivery means." In Millar et al., the substance 3 a is non-removable polymer "moulded" around the lobes of the body 1.

See Fig. 1 and col. 2, lns. 10-12 and 46-47. As such, the Millar device is not reusable and is not capable of "receiving and releasing" a substance delivery means.

Furthermore, nowhere in Millar et al. is it disclosed that the lobes of the body 1 are "biased outward" from a central section. Nor does the Examiner explain the reasons why the lobes of the body must necessarily and inevitably "biased outward" from a central section.

For at least these reasons, neither Klatt et al. nor Millar et al. anticipates independent claim 1.

Regarding the rejection of dependent claim 11 under § 103(a), the Examiner has failed to make a *prima facie* case of obviousness. As explained above, Klatt et al. fails to disclose all of the elements recited in independent claim 1. Moreover, the Examiner neither cited another reference making up for the deficiencies in Klatt et al. nor provided legally sufficient motivation or suggestion to modify the device of Klatt et al. in a manner resulting in the claimed invention.

Specifically regarding dependent claim 11, the Examiner acknowledges that Klatt et al. fails to disclose a support frame made of "nylon," but nonetheless alleges that the use of a nylon support frame would have been an obvious design choice. The Examiner, however, fails to explain legally sufficient motivation or suggestion to use nylon instead of the materials disclosed in Klatt et al. In fact, the manufacturing process for the Klatt device would preclude the use of nylon because the melting point of nylon is lower than that of the non-removable polymer incorporated onto the device. It is for this reason, Klatt et al. discloses, for example, polypropylene or polyethylene as appropriate materials for the device.

For at least these reasons, the Examiner has failed to establish a *prima facie* case of obviousness regarding independent claim 1 or any claims depending therefrom, including dependent claim 11.

In view of the foregoing remarks, Applicant submits that independent claim 1 as well as claims 2-9, 11-14, and 17-19 depending therefrom are in condition for allowance. Applicant therefore requests the Examiner's reconsideration and reexamination of the application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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